FORM B

REGISTRATION OF RESEARCH WITH RECOMBINANT DNA MOLECULES

IBC #: _____ **PATHOGEN #:** _____ **ANIMAL STUDY PROPOSAL #:** -

DATE RECEIVED: _____ **APPROVAL DATE:** _____

DO NOT WRITE IN ABOVE SPACE

****

1.Principal Investigator: _____ Telephone: _____

Bldg/Rm: _____ Organization: _____ Program: _____

Project Title: _____

2. Attach a written description of the proposal. The description should address the following issues:

A) Name of host (cloning vehicle).
B) Use of animals (attach a copy of the Animal Study Proposal).
C) Nature of gene sequence inserted in the recombinant.
D) Use of virus. This should include:
   1. Quantity.
   2. Use.
   3. Ability of the virus to replicate.
   4. Ability of the virus to infect human cells.
   5. Classification.
E) Name and use of vectors.
F) Potential hazards associated with this protocol.
G) Describe equipment and procedures used to safely conduct this protocol.

3. Are recombinant organisms/molecules:

A. Genetically modified microorganisms or genetic elements from organisms listed on the CDC List of Select Agents (42 CFR 72.6, Appendix A) shown to produce or encode for a factor associated with a disease? YES [ ] NO [ ]

B. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on the CDC List of Select Agents (42 CFR 72.6, Appendix A), or their toxin subunits? YES [ ] NO [ ]

4. Give specific reference for classification of your experiment:
(Use the current NIH Guidelines)

_____
(Section, Item, Page No.)

5. Have all personnel associated with this protocol been instructed and trained in the practices and techniques required to ensure safety and the procedures for dealing with accidents?
[ ] YES [ ] NO

If yes, please attach a roster of all personnel with signatures indicating that they fully understand laboratory practices and procedures to be followed.

6. List building and room(s) where work will be conducted (including animal work to support this protocol):

If an individual room has been designated for work at more than one Biosafety Level (i.e., BL1 and BL2), the highest degree of physical containment and work practice should apply at all times.

	Lab	Animal Facility
a) BL1	_____	_____
b) BL2	_____	_____
c) BL3	_____	_____

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To Be Completed by Animal Facility Manager (As applicable):

I attest that I have been informed of any potential hazards associated with this protocol and have informed my employees of the risks. All personnel associated with the protocol have been instructed of and will follow approved laboratory safety procedures.

_____ _____

Animal Facility Manager Signature Date

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I attest that the information contained in this application is accurate and complete. I agree to comply with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials. I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-4 of the NIH Guidelines.

I will not carry out the work described in the attached application until it has been filed with the IBC or, when necessary, until it has been approved by the Committee and all requirements have been met.

Principal Investigator _____ Date _____

DO NOT WRITE BELOW THIS LINE

This Registration Document is approved by the NCI-FCRDC Institutional Biosafety Committee.

_____ _____

Chairman, NCI-FCRDC, IBC Date

Note: Return Completed form to Biosafety, Bldg. 426
SAFETY, BSO
June 1997